Highlights of the 2016 OIG Work Plan

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Each fall, the Department of Health and Human Services Office of Inspector General (OIG) publishes its Work Plan for the upcoming fiscal year to summarize new and ongoing OIG reviews and initiatives. On November 2, 2015, the OIG posted its 2016 Work Plan to its website. The OIG's Work Plan sets forth the OIG's initiatives and priorities for the 2016 federal fiscal year (FFY) which the OIG will pursue through audits, investigations, inspections, industry guidance (including advisory opinions) and enforcement actions (including actions to impose civil monetary penalties, assessments, and administrative sanctions, such as exclusions). The 2016 OIG Work Plan includes the audits begun in years past that will continue into FFY2016 as well as the new audits scheduled to begin in FFY2016. There are a number of new starts for OIG audits and other reviews included in the 2016 OIG Work Plan, and we have highlighted a number of those below. You can view the initiatives that were scheduled to begin in FFY2015 and FFY2014.

New/Revised Hospital Initiatives

Medicare oversight of provider-based status

The OIG has revised this initiative, reflecting the continued scrutiny of provider-based facilities. In this revised review, the OIG will determine the number of provider-based facilities that hospitals own and the extent to which the Centers for Medicare & Medicaid Services (CMS) has methods to oversee provider-based billing. The OIG will also determine the extent to which provider-based facilities meet requirements described in 42 CFR Sec. 413.65 and CMS Transmittal A-03-030, and whether there were any challenges associated with the provider-based attestation review process.

Medical device credits for replaced medical devices

In this review, the OIG will determine whether Medicare payments for replaced medical devices were made in accordance with Medicare requirements. Medical devices are implanted during an inpatient or an outpatient procedure. Such devices may require replacement because of defects, recalls, mechanical complication, etc. Federal regulations require reductions in Medicare payments for the replacement of implanted devices (42 CFR §§ 412.89 and 419.45). This topic has been included in a number of the OIG's Medicare Compliance Reviews and hospitals have consistently

had problems in this area.

Medicare payments during MS-DRG payment window

The OIG will review Medicare payments to acute care hospitals to determine whether certain outpatient claims billed to Medicare Part B for services provided during inpatient stays were allowable and in accordance with the inpatient prospective payment system. Certain items, supplies, and services furnished to inpatients are covered under Part A and should not be billed separately to Part B (42 CFR §§ 409.10 and 410.3).

CMS validation of hospital-submitted quality reporting data

This review will focus on the extent to which CMS validated hospital inpatient quality reporting data. Section 1886(b)(3)(B)(viii)(XI) of the Social Security Act gives CMS the authority to conduct validation of its quality reporting program. CMS uses these quality data for the hospital value-based purchasing program and the hospital acquired condition reduction program. This review will also describe the actions that CMS has taken as a result of its validation.

Controls over networked medical devices at hospitals

The OIG will examine whether the FDA's oversight of hospitals' networked medical devices is sufficient to effectively protect associated electronic protected health information (ePHI) and ensure beneficiary safety. Computerized medical devices, such as dialysis machines, radiology systems, and medication dispensing systems that are integrated with electronic medical records and the larger health network, pose a growing threat to the security and privacy of personal health information because such medical devices use hardware, software, and networks to monitor a patient's medical status and transmit and receive related data using wired or wireless communications.

New Medicare Billing/Payment Initiatives

Medicare payments for unlawfully present beneficiaries in the United States

This review is required by Section 502 of the Medicare Access and CHIP Reauthorization Act of 2015 and will focus on a review of the procedures established by CMS to prevent and recoup Medicare payments for items and services furnished to unlawfully present beneficiaries in the United States.

Medicare payments for incarcerated beneficiaries — mandated review

This review is also mandated by Section 502 of the Medicare Access and CHIP Reauthorization Act of 2015 and will focus on a review of the procedures established by CMS to prevent and recoup Medicare payments for items and services furnished to incarcerated beneficiaries since Medicare will only pay for items and services where an incarcerated beneficiary has an obligation for the cost of care, which is

usually not the case.

CMS management of the ICD-10 implementation

The OIG intends to review aspects of CMS's early management of the implementation of ICD-10 codes in Medicare Parts A and B, including review of CMS's and its contractors' assistance and guidance to hospitals and physicians and assessment of how the transition to ICD-10 is affecting claims processing, including claims resubmissions, appeals, and medical reviews. The OIG may also review how ICD-10 diagnosis codes are being applied to selected CMS payment rules and safeguards (e.g., national or local coverage decisions related to coverable conditions).

New Initiatives for Medical Equipment Suppliers

Orthotic braces – reasonableness of Medicare payments compared to amounts paid by other payers

The OIG will review the reasonableness of Medicare fee schedule amounts for orthotic braces and compare Medicare payments made for orthotic braces to amounts paid by non-Medicare payers, such as private insurance companies, to identify potentially wasteful spending. The OIG will also estimate the financial impact on Medicare and on beneficiaries of aligning the fee schedule for orthotic braces with those of non-Medicare payers.

Osteogenesis stimulators – lump-sum purchase versus rental

The OIG intends to determine whether potential savings can be achieved by Medicare and its beneficiaries if osteogenesis stimulators are rented over a 13-month period rather than acquired through a lump sum purchase. These devices, also known as bone-growth stimulators, apply an electric current or ultrasound to the spine or a long bone (e.g., the femur) and are used when a fusion or fracture failed to heal or after a multilevel spinal fusion. Under current Medicare rules, because osteogenesis stimulators are categorized as "inexpensive and other routinely purchased items," the beneficiary has the option of either purchasing or renting the stimulators.

Orthotic braces – supplier compliance with payment requirements

The OIG will review Medicare Part B payments for orthotic braces to determine whether durable medical equipment, prosthetics, orthotics, and supplies claims were medically necessary and were supported in accordance with Medicare requirements.

Increased billing for ventilators

The OIG will examine billing trends for ventilators, Respiratory Assist Devices (RAD), and Continuous Positive Airway Pressure (CPAP) devices from 2011-2014, as well as examine factors associated with the increase in ventilator claims. This review was prompted by concerns expressed by CMS and its contractors about the increase in

billing for ventilators, specifically HCPCS code E0464 [a pressure support ventilator with volume control mode and a noninvasive interface (e.g., mask)]. The OIG will also examine the impact of the Competitive Bidding Program on ventilator billing trends.

New Nursing Home Initiatives

Skilled nursing facility prospective payment system requirements

The OIG will review compliance with various aspects of the skilled nursing facility (SNF) prospective payment system, including the documentation requirement in support of the claims paid by Medicare. Prior OIG reviews have found that Medicare payments for therapy greatly exceeded SNF's cost for therapy and that SNFs have increasingly billed for the highest level of therapy even though key beneficiary characteristics remained largely the same. The OIG will determine whether SNF claims were paid in accordance with Federal laws and regulations and that all documentation requirements specified in 42 CFR § 483.20 are met to ensure that SNF care is reasonable and necessary (77 Fed. Reg. 46214, 78 Fed. Reg. 47936). Such SNF documentation includes (1) a physician order at the time of admission for the resident's immediate care (2) a comprehensive assessment, and (3) a comprehensive plan of care prepared by an interdisciplinary team that includes the attending physician, a registered nurse, and other appropriate staff.

State agency verification of deficiency corrections

The OIG will determine whether state survey agencies verified correction plans for deficiencies identified during nursing home recertification surveys. CMS requires state survey agencies to verify the correction of identified deficiencies through onsite reviews or by obtaining other evidence of correction.

Revised Hospice Initiative

Hospice general inpatient care

The OIG will review the use of the general inpatient care (GIP) level of the Medicare hospice benefit and assess the appropriateness of hospices' GIP care claims and the content of election statements for hospice beneficiaries who receive GIP care. The OIG will also review hospice medical records to address concerns that GIP level of hospice care is being billed when that level of service is not medically necessary and to determine whether beneficiaries' plans of care meet key requirements. In addition, we will also determine whether Medicare payments for hospice services were made in accordance with Medicare requirements.

New Ambulatory Surgery Center Initiatives

Ambulatory surgical centers – quality oversight

The OIG intends to review Medicare's quality oversight of ASCs, including the length of time between certification surveys for some ASCs.

New Physician Initiatives

Physicians – referring/ordering Medicare services and supplies

The OIG will review select Medicare services, supplies and durable medical equipment referred/ordered by physicians and non-physician practitioners to determine whether the payments were made in accordance with Medicare requirements, including whether the physicians and non-physician practitioners who ordered the services, supplies and/or DME are Medicare-enrolled physicians or nonphysician practitioners and legally eligible to refer/order services, supplies and DME.

Anesthesia services – non-covered services

The OIG will review Medicare Part B claims for anesthesia services to determine whether the beneficiary had a related Medicare service since Medicare will not pay for items or services that are not "reasonable and necessary."

Physician home visits – reasonableness of services

The OIG intends to determine whether Medicare payments to physicians for evaluation and management home visits were reasonable and made in accordance with Medicare requirements. Physicians are required to document the medical necessity of a home visit in lieu of an office or outpatient visit as Medicare will not pay for items or services that are not "reasonable and necessary."

Prolonged services – reasonableness of services

The OIG will determine whether Medicare payments to physicians for prolonged E/M services were reasonable and made in accordance with Medicare requirements. Prolonged services are for additional care provided to a beneficiary after an evaluation and management service has been performed. Physicians submit claims for prolonged services when they spend additional time beyond the time spent with a beneficiary for a usual companion evaluation and management service. The necessity of prolonged services are considered to be rare and unusual.

Review of financial interests reported under the Open Payments Program

The OIG will determine the number and nature of financial interests that were reported to CMS under the Open Payments Program and examine the extent to which CMS oversees manufacturers' and GPOs' compliance with data reporting requirements and whether the required data for physician and teaching hospital payments are valid.

New Laboratory Initiatives

Histocompatibility laboratories – supplier compliance with payment requirements

The OIG will examine payments to histocompatibility laboratories to determine

whether the payments were made in accordance with Medicare requirements.

Revised Prescription Drug Initiatives

Part B payments for drugs purchased under the 340B Program

The OIG has revised this review to now focus on determining the financial impact on 340B-covered entities, the Medicare program, and Medicaid beneficiaries of three different shared savings arrangements that would enable Medicare and its beneficiaries to share in the cost savings resulting from 340B discounts. The OIG will also calculate the amount by which ASP-based payments exceed 340B prices.

Covered uses for Medicare Part B drugs

The OIG has revised this review to now focus on reviewing the oversight actions that CMS and its claims processing contractors take to ensure that payments for Part B drugs meet the appropriate coverage criteria. As part of this review the OIG intends to identify challenges contractors face when making coverage decisions for drugs to ensure that Medicare and its beneficiaries do not pay for drug uses that are not medically accepted.

Medicare Part D beneficiaries' exposure to inappropriate drug pairs

The OIG will determine whether Medicare Part D beneficiaries are being prescribed drugs that should not be prescribed in combination with other drugs, such as drugs that have a severe interaction when used in combination with other drugs and drugs that should not be co-prescribed with component drugs, i.e., drugs that contain more than one active ingredient and with one of the active ingredients prescribed individually.

Increase in prices for brand-name drugs under Part D

The OIG will evaluate the extent to which pharmacy reimbursement for brand-name drugs under Medicare Part D changed between 2010 and 2014 and compare the rate of change in pharmacy reimbursement for brand name drugs under Medicare Part D to the rate of inflation for the same period.

States' actions based on Medicaid and MCO drug utilization reviews

The OIG will review the education and enforcement actions that States have taken on the basis of information generated by their drug utilization review (DUR) programs related to inappropriate dispensing and potential abuse of prescription drugs, including opiates. We also will review State oversight of and coordination with MCOs' DUR programs and any resulting actions related to inappropriate dispensing of opiates.

New ACO Initiative

Accountable Care Organizations: Strategies and Promising Practices

The OIG will review ACOs that participate in the Medicare Shared Savings Program and examine their performance on the quality measures and cost savings over the first three years of the program, including describing the characteristics of those ACOs that performed well on measures and achieved savings. The OIG will also identify ACOs' strategies for and challenges to achieving quality and cost savings.

Revised Medicare/Medicaid Provider Enrollment Initiatives

State and CMS oversight of provider ownership information

The OIG is going to review the extent to which States collect required ownership information for provider entities enrolled in Medicare and Medicaid describe the extent to which they verify the collected information. The OIG also intends to determine whether States and CMS checked exclusions databases for enrolling and enrolled providers, as required and compare the ownership information that selected providers gave to States to enroll in Medicaid, and that providers gave to CMS to enroll in Medicare, to the ownership information that the same providers gave to OIG for the purposes of this study.

States' experiences with enhanced provider screening

The OIG will review whether states are conducting enhanced screenings that assess risk for fraud, waste, and abuse for moderate and high-risk enrolling and revalidating Medicaid providers and suppliers. The OIG will also determine the extent to which states have screened moderate and high-risk providers and suppliers using these risk-based screenings.

Provider payment suspensions during pending investigations of credible fraud allegations

The OIG plans to review payments to providers with allegations of fraud deemed credible by states and to examine states' use of payment suspensions since FFP in Medicaid is not available for items or services furnished by an individual or entity when the state has failed to suspend payments during a period when there is a credible allegation of fraud. In addition, the OIG plans to determine whether Medicaid state agencies are in compliance with requirements that states must suspend all Medicaid payments to the providers, unless the states have good cause to not suspend payments or to suspend payment only in part and that they make fraud referrals to Medicaid Fraud Control Units.

New Medicaid Managed Care Initiatives

Medical loss ratio – recoveries of MCO rebates from profit-limiting arrangements

The OIG will review states and managed care plans with contract provisions that require rebates from managed care plans if a minimum percentage of total costs to be expended for medical services (the medical loss ratio) is not met to ensure that the federal share of recoveries of MCO payments that states received through profit-

limiting methodologies is returned to the Federal Government.

Review of states' methodologies for assigning MCO payments to different Medicaid FMAPs

The OIG will review methodologies for assigning MCO payments to different Medicaid FMAPs (e.g., the regular FMAP, the family planning FMAP, the Indian Health Services FMAP, etc.).

Managed long-term-care reimbursements

The OIG intends to examine states' reimbursements made to managed long-term-care (MLTC) plans to determine whether those reimbursements complied with certain federal and state requirements.

If you have questions about the OIG's 2016 Work Plan and planned initiatives, please contact Shannon DeBra (sdebra@bricker.com, 513.870.6685) or any member of the Health Care practice group.